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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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08/412,114

03/28/1995

ZBYLUT J. TWARDOWSKI

08366.0005-00000

4355

22852

7590

07/06/2009

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EXAMINER

MENDEZ, MANUEL A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

07/06/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 08/412,114	<b>Applicant(s)</b> TWARDOWSKI ET AL.	
	<b>Examiner</b> Manuel A. Mendez	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 19-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 19-76 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/06/2009, 10/14/2008, and 03/28/1996</u> .                  | 6) <input type="checkbox"/> Other: _____                          |



## DETAILED ACTION

### *Allowable Subject Matter*

**Claims 1 and 19-76** are allowable over the prior art of record.

The following is a statement of reasons for the indication of allowable subject matter:

In relation to **claim 1**, the prior art of record does not disclose or suggest, a catheter for hemodialysis which comprises a flexible catheter tube defining a plurality of separate lumens, said catheter defining an arc angle of generally U-shape in its natural, unstressed configuration, whereby said catheter may be implanted with a distal catheter portion residing in a vein of a patient, said distal catheter portion being of substantially the shape of said vein in its natural, unstressed condition, and a proximal catheter portion residing in a surgically created tunnel extending from said vein and through the skin of the patient, whereby blood may be removed from said vein through one lumen of the catheter and blood may be returned to said vein through another lumen of the catheter.

In relation to **claim 19**, the prior art of record does not disclose or suggest, a flexible catheter for prolonged vascular access, the catheter comprising: an elongate flexible and tubular body having a proximal portion, a distal portion and a permanently curved portion linking the proximal and distal portions so that the curved, the proximal and the distal portions lie naturally in essentially the same plane with the angle contained between the proximal and distal portions being less than 90°, and a septum extending continuously through said portions and lying substantially at right angles to said plane to divide the tubular body into generally D-shaped intake and outlet lumens; intake and outlet tubes coupled to the proximal portion at a proximal end of the body remote from the curved portion to receive incoming fluid from the intake lumen and to supply outgoing fluid to the outlet lumen; and a tip formed on the distal end of the distal portion and including at least one intake opening for receiving the incoming fluid and at least one outlet opening for returning the outgoing fluid.

Finally, in relation to **claim 38**, the prior art of record does not disclose or suggest, a flexible catheter for prolonged vascular access, the catheter comprising: an elongate flexible and tubular body having a proximal portion, a distal portion and a permanently curved portion linking the proximal and distal portions so that the curved, the proximal and the distal portions lie naturally in essentially the same plane with the angle contained between the proximal and distal portions being less than 90°; intake and outlet tubes coupled to the proximal portion at a proximal end of the body remote from the curved portion to receive incoming fluid from the intake lumen and to supply outgoing fluid to the outlet lumen; and a tip formed on the distal end of the distal portion

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and including at least one intake opening for receiving the incoming fluid and at least one outlet opening for returning the outgoing fluid.

### ***Conclusion***

This application is in condition for allowance except for the following formal matters:

On the final review to place this application in condition of allowance, the new examiner of record noticed that there is a pending objection to the drawings dated December 28, 1995. It appears that the draftsman concluded that the margins of the drawings submitted on March 28, 1995; do not comply with the specified margin requirements. Accordingly, submittal of new drawings is hereby respectfully requested.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 25 USPQ 74, 453 O.G. 213, (Comm'r Pat. 1935).

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel A. Mendez whose telephone number is 571-272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Manuel A. Mendez/

Primary Examiner, Art Unit 3763

Manuel A. Mendez  
Primary Examiner  
Art Unit 3763

MM